National Committee of Bioethics (NCBE)

Informed Consent

Informed Consent Requirements:

No investigator should initiate experiments of any research studies on humans until an informed consent has been obtained from the subject or his/her legal guardian. Such consent must be based upon the provisions set forth in the relevant approved executive by-laws. Informed consent must be requested in the manner that would allow the subject or his/her legal guardian the time to think and not to take a hasty decision of approval until after all risks, benefits and their acceptance have been assessed without any compulsion or surrender to excessive attraction.

1. Patients who are subject to research study must know all information related to the nature of study and the scope of their participation therein. They must be completely free to accept or refuse to participate and should also be given the opportunity to withdraw from participation any time they may elect to.
2. Risks or detriments (if any) which may ensue from their withdrawal from the study, should be made clear in the consent form.
3. Informed consent to participate in a research project would be only accepted from individuals who have been fully informed of the complete project and had all their questions satisfactorily answered.

4. Informed consent should be requested by an individual who would be fully aware of all aspects of the project. Such aspects must include reasons for conducting the project, qualification requirements, criteria for exclusion, procedures to be made, cost, possible risks, benefits to be obtained from participation, period of participation, alternatives, etc.
5. Informed consent must be taken at the time which allows the individual nominated to participate in the study the time to think and decide with all options given to him after explaining the needed information (verbally and in writing) and answering all his/her questions.
6. Consent form must include a statement to indicate that participation in the study is completely voluntary and that refusal to participate should in no way result in a penalty or loss of benefits the subject patient is entitled for. It should also indicate that the subject has the right to withdraw from the study at any of the research project stages without any loss of benefits which he/she might be eligible for.

Selection of Participants

Research project submitted to the local committee must identify the method of selecting participating individuals.

Approval of patient to participate in the research project must be taken by the attending physician before the patient has been enrolled in the study. In such cases, personal permit or comprehensive consent must be obtained

from patient by the attending physician (preferably in writing). After that investigator can personally meet with the patient without prior notice. He should indicate to the patient the approval of his attending physician to communicate with the patient. Attending physician should be informed of same.

Guidelines for Consent Form:

Only forms that are officially dated must be used. Such forms which carry approval dates of the local committee to conduct study on human subjects.

Upon obtaining local committee approval, consent forms of participation in the study must be incorporated with the approved period of study. In case of financial support, the consent form must remain valid throughout the support budget period. Under no circumstance will the consent form be used after expiration of the completion date specified for the research study.

All information needed to be known by participating patients, scope of participation as well as patient signature indicating that he/she has read and fully understood the form, must be enclosed with all forms used to obtain written consent.

Consent form, however, should not include any phrases that may excuse the investigator from responsibility which may make the institution or its representative appear elusive of legal rights or uncommitted to shoulder

any negligence-ensuing responsibly whether on the investigator, institution or representative's part.

Specific contact number (local committee) must be put down in the form to enable the subject to call in case of any problem or complaint.

Basic Elements of Informed Consent

Information presented to research subject must include the following:

1. Explicit indication that the requested consent means participation in the study. It must state objectives of the project, identify the time expected for its completion, detailed description of its various stages, particularly the experimental part, with a list of participating, supporting or organizing institutions and those who may benefit from project's results.
2. Indicate all procedures and medical treatments associated with the project or those which would be only conducted for this purpose and whether they may have any long or short-term risks to the subject (or the fetus).
3. Describe any unexpected risks or inconvenience that may happen to the subject.
4. Describe any possible benefits the subject may gain out of the study.
5. Describe treatment modalities available outside the scope of study.
6. Indicate that confidentiality of patient's personal information would be maintained.

7. Indicate any financial compensation or medical treatment for injuries which may result from the study, if such research can expose the subject to risks that may exceed minimum range.
8. Indicate the person who could be contacted to obtain information related to the project or to the subject's lawful rights; and the way to report any injury the subject may sustain that would be associated with the research study.
9. Indicate expected conditions under which the investigator can end the subject's participation in the study without his/her approval.
10. Indicate any regular or additional cost the subject may have to bear due to his/her participation in the study.
11. Indicate the negative outcomes that may ensue from the subject's decision to withdraw from the study and explain the best way for withdrawal.
12. Make a commitment that the subject would be kept informed of all important information which may come up during the course of study, which may affect continuity of his/her participation in the project.
13. Identify the approximate number of persons who will be subjected to the study.
14. Indicate the risks of discontinuing subject's previously prescribed medications should the project so requires.

In certain cases, some of the above conditions can be dropped in the informed consent, under specific circumstances which require the

investigator to request revision of the informed consent form and such request must be approved by the Local Research Ethics Committee

Responsibility for Obtaining Informed Consent:

- Obtaining an informed consent is the responsibility of the principal investigator. He/she may designate one of his/her assistants who would be fully aware of all aspects of the project and can answer subject's questions. In case an extraordinary procedure is required, which is not common in patient care or can expose the subject to risks that exceed the minimum range, in such a case obtaining an informed consent will be the responsibility of the principal investigator or the individual who would be conducting that particular procedure.
- When it becomes infeasible for the principal investigator or any of his/her assistant to personally obtain the informed consent, he/she can explain these special circumstances in a request submitted to the Local Committee to designate another individual(s) who would be aware of the nature of the study to obtain such a consent. The Committee may accept or refuse such a request in accordance with the justifications submitted by the investigator.

Time and Place of Obtaining Informed Consent:

The circumstances under which informed consent is obtained must allow the subject to take his/her time to understand the issue and to decide on his/her own volition away form any compulsion that might be represented in the shortness of time or feeling of need or psychological or social

embarrassment. It is important to indicate in the research project the circumstances under which the informed consent would be obtained.

How to Obtain Informed Consent:

- Information contained in the informed consent form must be made available to the individual nominated to participate in the study. It should be conveyed to him/her verbally and in writing with all his/her questions answered. The subject must put his/her signature in the designated place on the form. The investigator will also put his/her signature indicating date and time in writing.
- The subject is to be given one copy of the consent form with another copy placed in patient's chart (if subject has a medical chart). Original consent form will be kept, after signing, in the maintained records of the project. He/she must present it, when so requested, to the Research Ethics Control Office.

Needed Signatures:

1. Signature of the individual participating in the study or his/her legal guardian.
2. Two (2) witnesses' signatures are needed only when the individual nominated to participate in the study gives his/her consent verbally because of his/her inability to read the consent form.
3. Signature of the investigator or his/her designee as per approval of the Local Research Ethics Committee.

Validity of Informed Consent:

Informed consent will be valid throughout the research period as approved by the Committee, unless any of the following has occurred:

1. Alteration or revision effected on the informed consent form after its signing.
2. Participating child has reached the age where he has become able to give his/her own consent.
3. If no specific period is indicated in the signed consent form, consent would be considered void, and consequently a new consent would be needed.

The Local Committee may verify correctness of consent obtaining procedures and may designate someone to monitor issuance of such consent forms.

Investigator must provide information to the subject in an understandable language with no ambiguity of text.

Documentation of Informed Consent

Informed consent is to be documented by the investigator (or his/her) designee and the subject (or his/her legal guardian) using the form approved by the Local Committee. Copy of the consent document is to be given to the signing person.

Local Committee may exempt the investigator from taking a written informed consent form and the signing thereof if all of the following conditions have been met:

1. If project does not expose the subject to more than minimum risk range.
2. If investigator proves that the research cannot practically be conducted without exempting him/her from the written consent condition.
3. If it is impossible for the research to jeopardize rights and interest of the subject.
4. If subjects would be informed of the needed information, if deemed necessary.

If the above conditions are met, principal investigator is to submit a request to the Local Committee informing them that the above conditions have been met and that he/she must be exempted from the written consent condition.

Examples of Conditions to Exempt Investigator from Written Consent Form:

1. Application of written questionnaires, as acceptance of completed questionnaire forms is regarded as an implicit consent.
2. Conducting an interview to clarify certain information.
3. Collecting additional blood or body fluid specimens for medical care purposes not associated with the study such that collection of these

specimens would not expose the subject to more than the minimum risk range. This, however is not applicable to genetics research.

Under these circumstances, a research explanation form must be made available and must be given or read to the patient with no need for his signing. It should be documented in the investigator's record that this procedure was conducted after patient's verbal consent had been obtained.

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